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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,451

09/09/2003

Maria Villani

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02/23/2009

K&L Gates LLP

1900 MAIN STREET, SUITE 600

IRVINE, CA 92614-7319

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,451	<b>Applicant(s)</b> VILLANI, MARIA	
	<b>Examiner</b> Kailash C. Srivastava	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

1. The response, remarks and amendment filed 16 October 2008 to the Office Action with Notice of Non-Compliant Amendment mailed 06 October 2008 is acknowledged and entered.
2. The following Office Action addresses Applicant's responses filed 26 August and on 16 October 2008 as well as takes into consideration all the discussions between the Examiner, Applicant's Representative, Applicant and Examiner's Supervisor in the interviews held respectively on 13 November 2008 and on 07 January 2009.

### **Objections/Rejections Withdrawn**

3. In view of remarks and amendment filed 26 August and on 16 October 2008, following rejections in the Office Action mailed 30 April 2008 are hereby withdrawn.

- Anticipatory rejections to Claims 1-3 and 24-25 under 35 U.S.C. §102(b) as anticipated by Reka Farm (printed from [http://www.reka-farm.ru/prod\\_e.htm](http://www.reka-farm.ru/prod_e.htm) 4/14/2008 4:53:43 PM).
- Obviousness rejection to Claims 1, 3, 7 and 24-25 under 35 U.S.C. § 103 (a) as obvious over combined teachings from Reka Farm (printed from [http://www.reka-farm.ru/prod\\_e.htm](http://www.reka-farm.ru/prod_e.htm) 4/14/2008 4:53:43 PM) in view of Manconi et al ((2008. Global diversity of sponges (Porifera: Spongillina) in freshwater, *Hydrobiologia*, Volume 595 Page 27–33) and further in view of Philippe et al (US Patent 7, 078, 047).

### **Claims Status**

4. Claims 2, 4-6, 8-23 and 26-27 remain cancelled.
5. Claim 1 has currently been amended.
6. Claims 1, 3, 7 and 24-25 are currently pending and are examined on merits.

### ***Claim Rejections Under 35 U.S.C. §103(a)***

7. In view of the amendments to Claim 1 and remarks filed 26 August and on 16 October 2008, following is a new rejection to Claims 1, 3, 7 and 24-25.

8. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

9. Claims 1, 3, 7 and 24-25 are rejected under 35 U.S.C. § 103(a) as obvious over combined teachings from Schröder, (1942. "Die Verwendung der Süßwasserschwamme in der Ukraine" Die 3, Umschau Wissenschaft Technik 46: 507-509) in view of Philippe et al (US Patent 7, 078, 047).

Claims 1, 3, 7 and 24-25 recite a pharmaceutical composition comprising a substantially pure powder of a freshwater sponge having 50-60% insoluble material and particle size of no more than 0.2 mm and a pharmaceutically acceptable excipient, wherein said freshwater sponge is *Spongilla lacustris*. The claimed pharmaceutical excipient is floral water. Said composition is applicable for treating skin diseases e.g., dermatitis and acne.

Regarding Claims 1, 3, 7, and 24-25, Schröder teaches a powder of fresh water sponges, wherein one of the sponge is *Spongilla lacustris* (Page 507, Figure 3; Page 507, Column 2, Line 33). Said powder is obtained by comminuting said fresh water sponge and said powder is soluble in 90% alcohol (Page 508, Column 1, Lines 1-15). Note comminution would produce powder having a particle size of up to 0.2 mm. Furthermore, as stated in the specification of instant application at paragraphs 0068 and 0093, the applicant also prepares the instantly claimed composition through comminution of the dried sponge and subsequent sieving (i.e., the prior art applies the same steps as are utilized in the instantly claimed invention at paragraph [0068]). Schröder, however, is silent regarding the insolubility of the fresh water sponge powder. Despite this silence, the fresh water sponge powder of the prior art would inherently have the same properties (i.e., approximately 50-60% insoluble material and a maximum particle size of 0.2 mm) as instantly claimed because the prior art composition is comprised of same components prepared in the same way as the claimed composition (See e.g., In re Best, 195 USPQ 430, 433-CCPA 1977). Schröder is also silent regarding the excipient to be specifically floral water. Phillippe et al. teaching a pharmaceutical composition for skin treatment (See Abstract) further teach mineral water or floral water to be the excipient (Column 5, Line 11). Furthermore, the functional intended use of a composition is not given any patentable weight because those parameters would essentially not change the composition itself.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Schröder in view of the teachings from Philippe et al., to obtain a composition comprising a substantially pure powder of a fresh water sponge having 50%-60% insolubility and a particle size of no more than 0.2 mm and at least one pharmaceutically acceptable excipient, wherein said powder is a powder of *Spongilla lacustris* in a floral water excipient; because Philippe et al. teach the excipient to be the floral water.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify Schröder's teachings with those of Philippe et al., to obtain a composition comprising a powder of freshwater sponge, especially *Spongilla lacustris* with at least one pharmaceutically acceptable excipient, wherein said excipient is floral water; because Philippe et al., teach floral water as a pharmaceutically acceptable excipient.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### Conclusion

10. For the aforementioned reasons, no claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Kailash C Srivastava/  
Examiner, Art Unit 1657

Kailash C. Srivastava  
Patent Examiner  
Art Unit 1657  
(571) 272-0923

16 February 2009

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657